

IN THE CLAIMS

1. (currently amended) A method for diagnosing an ovarian cancer in a mammal, comprising:

detecting and measuring the hepsin gene copy number in a ~~biological sample obtained from a region~~ of ovarian tissue ~~isolated from~~ of the mammal that is suspected to be precancerous or cancerous, thereby generating data for a test gene copy number; and

comparing the test gene copy number to data for a control gene copy number, wherein a detectable increase in amplification of the gene in the ~~biological sample~~ of the ovarian tissue relative to the control indicates the presence of a precancerous ovarian lesion or an ovarian cancer in the mammal.

2. (canceled)

3. (previously presented) The method according to claim 1, wherein at least one of the data for the test gene copy number or the data for the control gene copy number are stored in a data storage medium selected from the group consisting of paper, electronic mail, disk, compact disk (CD), digital versatile disk (DVD), memory card, memory chip, ROM, RAM, magnetic optical disk, tape, video, video clip, microfilm, internet, shared network, and shared server.

4-8. (canceled).

9. (currently amended) A method for monitoring the efficacy of a therapeutic treatment regimen in a patient, comprising:

measuring the hepsin gene copy number in a first sample of precancerous ovarian cells or ovarian cancer cells ~~isolated~~ obtained from a patient at a first time point in a treatment regimen;

measuring the hepsin gene copy number in a second sample of precancerous ovarian cells or ovarian cancer cells isolated ~~obtained~~ from the patient at a second time point in the treatment regimen; and

comparing the gene copy number in the first and the second samples, wherein data showing a detectable decrease in the gene copy number levels in the second sample relative to the first sample indicates that the treatment regimen is effective in the patient.

10. (canceled)

11. (previously presented) The method according to claim 9, wherein data representing the hepsin gene copy number in at least one of the first and second samples are stored in a data storage medium selected from the group consisting of paper, electronic mail, disk, compact disk (CD), digital versatile disk (DVD), memory card, memory chip, ROM, RAM, magnetic optical disk, tape, video, video clip, microfilm, internet, shared network, and shared server.

12-21. (canceled)

22. (currently amended) A method for monitoring the efficacy of a therapeutic treatment regimen in a patient, comprising:

measuring a first expression level of at least one of hepsin mRNA or hepsin protein in a first tissue sample ~~of a biological sample~~ comprising precancerous or cancer cells isolated ~~obtained~~ from a patient at a first time point in a treatment regimen, wherein the ~~biological first~~ tissue sample comprises ovarian, prostate, or lung tissue;

measuring a second expression level of at least one of hepsin mRNA or hepsin protein in a second tissue sample ~~of the biological sample obtained~~ isolated at a second time point in the treatment regimen; and

comparing the first and second expression levels, wherein a detectable decrease in the second expression level relative to the first expression level indicates that the treatment regimen effectively reduced the number of precancerous or cancer cells in the second tissue biological sample relative to the first sample,

wherein each of the first and second tissue samples comprises ovarian tissue, or each of the first and second tissue samples comprises prostate tissue, or each of the first and second tissue samples comprises lung tissue.

23. (canceled)

24. (previously presented) The method according to claim 22, wherein data representing at least one of the first and second expression levels are stored in a data storage medium selected from the group consisting of paper, electronic mail, disk, compact disk (CD), digital versatile disk (DVD), memory card, memory chip, ROM, RAM, magnetic optical disk, tape, video, video clip, microfilm, internet, shared network, and shared server.

25-38. (canceled)

39. (previously presented) The method according to claim 1, wherein the detectable increase in amplification is about 2.5 fold.

40. (previously presented) The method according to claim 9, wherein the detectable decrease in the amplification is about 2.5 fold.

41. (canceled)

42. (previously presented) The method according to claim 22, wherein the detectable decrease in the second expression level is about 5.0 fold.

43. (canceled)

44. (previously presented) The method of claim 1 wherein the mammal is a human.
45. (previously presented) The method of claim 9 wherein the patient is a human.
46. (canceled)
47. (previously presented) The method of claim 22 wherein the patient is a human.
- 48-51. (canceled)
52. (currently amended) A method for diagnosing ovarian cancer in a mammal, comprising:
- determining a hepsin gene copy number in a ~~biological sample obtained from a~~
~~region~~ of ovarian tissue isolated from ~~of~~ the mammal which is suspected to be precancerous or cancerous, wherein amplification of the hepsin gene copy number relative to a control hepsin gene copy number indicates the presence of cancer or a precancerous lesion in the mammal.
53. (previously presented) The method of claim 52 wherein the mammal is a human.
- 54-57. (canceled)
58. (previously presented) The method of claim 52 wherein data representing the hepsin gene copy number is stored in a data storage medium selected from the group consisting of paper, electronic mail, disk, compact disk (CD), digital versatile disk (DVD), memory card, memory chip, ROM, RAM, magnetic optical disk, tape, video, video clip, microfilm, internet, shared network, and shared server.

59. (currently amended) A method for diagnosing an ovarian cancer in a mammal, comprising:

determining a first indirect measure of hepsin gene copy number in a ~~biological sample obtained from a region~~ of ovarian tissue isolated from of the mammal that is suspected to be precancerous or cancerous; and

comparing the first indirect measure to a second indirect measure of a control gene copy number in a control tissue ~~biological~~ sample, wherein a detectable change in the first indirect measure relative to the second indirect measure indicates the presence of a precancerous lesion or a cancer in the mammal.

60. (previously presented) The method of claim 59 wherein the first and second indirect measures are determined by real-time quantitative RT-PCR and the detectable change is a detectable decrease.

61. (previously presented) The method of claim 59 wherein the first and second indirect measures are determined by fluorescence *in situ* hybridization (FISH) and the detectable change is a detectable increase.

62. (currently amended) A method for monitoring the efficacy of a therapeutic treatment regimen in a patient, comprising:

determining a first indirect measure of hepsin gene copy number in a first sample of ~~a biological sample~~ tissue comprising precancerous ovarian cells or ovarian cancer cells ~~obtained~~ isolated from a patient at a first time point in a treatment regimen;

determining a second indirect measure of hepsin gene copy number in a second sample of ~~the biological sample obtained~~ tissue isolated at a second time point in the treatment regimen; and

comparing the first and second indirect measures, wherein a detectable change in the second indirect measure relative to the first indirect measure indicates that the treatment regimen effectively reduced the number of precancerous or cancer cells in the tissue ~~biological~~ sample.

63. (previously presented) The method of claim 62 wherein the first and second indirect measures are determined by real-time quantitative RT-PCR and the detectable change is a detectable decrease.

64. (previously presented) The method of claim 62 wherein the first and second indirect measures are determined by fluorescence *in situ* hybridization (FISH) and the detectable change is a detectable increase.

65. (previously presented) The method of claim 59 wherein the mammal is a human.

66. (previously presented) The method of claim 62 wherein the patient is a human.

67. (previously presented) The method of claim 44 wherein the hepsin gene encodes the amino acid sequence SEQ ID NO:2.

68. (previously presented) The method of claim 67 wherein the hepsin gene comprises the nucleotide sequence SEQ ID NO:1.

69. (previously presented) The method of claim 45 wherein the hepsin gene encodes the amino acid sequence SEQ ID NO:2.

70. (previously presented) The method of claim 69 wherein the hepsin gene comprises the nucleotide sequence SEQ ID NO:1.

71-72. (canceled)

73. (previously presented) The method of claim 47 wherein the hepsin gene encodes the amino acid sequence SEQ ID NO:2.

74. (previously presented) The method of claim 73 wherein the hepsin gene comprises the nucleotide sequence SEQ ID NO:1.

75-76. (canceled)

77. (previously presented) The method of claim 53 wherein the hepsin gene encodes the amino acid sequence SEQ ID NO:2.

78. (previously presented) The method of claim 77 wherein the hepsin gene comprises the nucleotide sequence SEQ ID NO:1.

79. (previously presented) The method of claim 65 wherein the hepsin gene encodes the amino acid sequence SEQ ID NO:2.

80. (previously presented) The method of claim 79 wherein the hepsin gene comprises the nucleotide sequence SEQ ID NO:1.

81. (previously presented) The method of claim 66 wherein the hepsin gene encodes the amino acid sequence SEQ ID NO:2.

82. (previously presented) The method of claim 81 wherein the hepsin gene comprises the nucleotide sequence SEQ ID NO:1.